
Federal Court of Australia decides in favour of Myriad

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1. Introduction

The recent Australian decision in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) now confirms that isolated genes and other biological materials constitute patentable subject matter, and that no distinction should be made between different biological materials on the basis of inherent “informational” characteristics. In addition, it was held that there is no requirement for any physical / chemical change to have occurred during the process of isolation. Significantly, this Federal Court decision represents the first court case in Australia to consider the patentability of genetic material.²

2. Requirements for patentable subject matter in Australia

To encompass patentable subject matter under Australian law, an invention must satisfy section 18(1)(a) of the *Patents Act* 1990 which requires that a claimed invention be “a manner of manufacture”. Previous Australian case law has long established that in order for an invention to be “a manner of manufacture”, it must give rise to (1) an artificially created state of affairs that is (2) in a field of economic endeavour.³ In making this assessment, the patent office or courts will not enquire into matters of ethics or social policy.⁴

In order to satisfy the requirement for “an artificially created state of affairs”, claims encompassing naturally occurring biological materials must distinguish that material from the form in which it already exists in nature. For example, in relation to genes, claiming “isolated” or “purified” nucleic acids or recombinant nucleic acids has traditionally been

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2. This Australian decision is to be contrasted to the United States decision in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), which was successfully appealed in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 10-1406 (Fed. Cir. Aug. 16, 2012). *Cert. granted 16 August 2012*;

3. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (the “NRDC Case”);

4. *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) 28 IPR 383;

allowed by the patent office on the basis that the act of isolating, purifying or cloning satisfies the requirement that a patentable invention give rise to “an artificially created state of affairs”. The underlying rationale is that an isolated, purified or recombinant nucleic acid does not exist in nature, but rather, that nucleic acid only exists in nature in a different form, for example, as part of a chromosome. A similar rationale has generally been applied by the patent office to claiming other naturally occurring biological materials such as isolated proteins, which may only exist in nature as part of a cell or organism.⁵

In order to satisfy the requirement that there be “a field of economic endeavour”, the patent office has traditionally required that a claimed nucleic acid or amino acid should have a function or putative function ascribed to it, or be described as useful for a particular purpose, such as for methods of treatment or diagnosis. Hence, for example, claiming of expression sequence tags (ESTs) has proven difficult.

Under section 18(2) of the *Patents Act* (1990), there already exists a specific ban on patenting “human beings, and the biological processes for their generation”. This has been interpreted by the patent office to include totipotent stem cells, but not pluripotent / multipotent stem cells, due to the difference in the potential of each of these cell types to create a human being.⁶ Accordingly, section 18(2) cannot be regarded as precluding *per se* the patentability of other biological materials such as a nucleic acid or amino acid that cannot of itself give rise to a human being.

3. The Myriad case in the Federal Court of Australia

The Federal Court case involved an allegation of the invalidity of claims 1-3 of Australian patent no. 686,004 owned by Myriad Genetics, Inc. and licensed to Genetic Technologies Ltd, on the basis that the claimed subject matter was not “a manner of manufacture” as required by section 18(1) of the *Patents Act* (1990). The claims at issue were drawn to isolated nucleic acids, and because both parties acknowledged that the claimed subject matter

5. *Ranks Hovis McDougall Ltd's Application* (1976) AOJP 3915;

6. *Fertilitescentrum AB and Luminis Pty Ltd's Application* [2004] APO 19 (13 July 2004); *Woo-Suk Hwang* [2004] APO 24 (9 September 2004);

was “in a field of economic endeavour”, the question to be heard by the court centred on whether claims to an isolated nucleic acid constituted “an artificially created state of affairs”.

The court took expert evidence on the issue of whether or not an isolated nucleic acid was essentially the same as a nucleic acid *in vivo*, and the processes required to isolate a nucleic acid from a cell. The term “isolated” was defined in the specification as:

An “isolated” or “substantially pure” nucleic acid (e.g., an RNA, DNA or a mixed polymer) is one which is substantially separated from other cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, many other human genome sequences and proteins. The term embraces a nucleic acid sequence or protein which has been removed from its naturally occurring environment, and includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.

The judge noted that the disputed claims were not drawn to genetic information *per se*, but to tangible materials,⁷ and pointed out that the claims could never be infringed by someone who merely reproduced a DNA sequence in written or digitised form. In addition, the judge noted that because the claims were drawn to an isolated chemical composition, naturally occurring nucleic acids as they exist in a cell are not within the scope of the disputed claims.

In determining whether the claims constituted the requisite “artificial state of affairs”, the judge was of the opinion that the claimed composition of matter must be the result of some human intervention, but that there is no requirement to ask whether the composition of matter is a “product of nature” or “markedly different” to something that already exists in nature.⁸ Hence, in relation to claimed biological material, the judge was of the opinion that the requisite “artificial state of affairs” may be satisfied by the removal of the material from its natural environment and its separation from other cellular components, even if the physical properties of the material have not changed.⁹

7. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 76;

8. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 103;

9. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 104;

In holding that the claims did constitute an artificial state of affairs, the judge set down three key considerations: (1) the test for what constitutes an artificial state of affairs is deliberately expansive and should be interpreted broadly; (2) isolated nucleic acid is the product of human intervention involving the extraction and purification of the nucleic acid, as per the definition of “isolated” in the specification; and (3) it would be a mistake if a person whose skill and effort culminated in the isolation of a nucleic acid could not be independently rewarded by the grant of a patent because the isolated nucleic acid, no matter how practically useful or economically significant, was held to be inherently non-patentable.¹⁰

The judge also supported the decision by noting the lack of a ban on patenting nucleic acids under section 18(2) of the *Patents Act* (1990) (as discussed above) and the recent failure of proposed legislation to ban gene patenting,¹¹ with the judge concluding that it was the intention of the legislature for the issue of gene patenting to be determined in accordance with established case law principles.¹² In addition, it was noted that the patentability of nucleic acids would not prevent experimental use, due to the new experimental use defence against alleged infringement that was recently enacted in the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012.¹³

4. Conclusion

Patent applicants seeking to claim genetic and other biological materials should be assured that such subject matter has been strongly affirmed as being patentable under Australian law. In combination with the recent defeat of proposed legislative amendments to ban patenting of such subject matter,¹⁴ this first decision by the Australian Federal Court on the patentability of genetic material consolidates the position adopted for many years by the Australian patent office and therefore provides greater certainty to patent applicants.

10. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 105;

11. *Patent Amendment (Human Genes and Biological Materials) Bill* (2010);

12. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at paras 111-112;

13. *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (15 February 2013) at para 121

14. *Patent Amendment (Human Genes and Biological Materials) Bill* (2010).
